

Exhibit 16

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended June 30, 2001

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (D)
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 1-9898

ORGANOGENESIS INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation or organization)

04-2871690

(I.R.S. Employer
Identification number)

150 DAN ROAD, CANTON, MA

(Address of principal executive offices)

02021

(Zip Code)

Registrant's telephone number, including area code: (781) 575-0775

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes (X) No ()

The number of shares outstanding of registrant's Common Stock, par value \$.01 per share, at August 1, 2001 was 34,789,137 shares (excluding treasury shares).

ORGANOGENESIS INC.

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In this report, "Organogenesis" "we" "us" and "our" refer to Organogenesis Inc.	

PART I - FINANCIAL INFORMATION
Item 1 - Financial Statements

ORGANOGENESIS INC.

Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2000	June 30, 2001
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 9,539	\$ 2,549
Restricted cash	-	5,000
Investments	2,644	-
Inventory	1,377	1,570
Receivable from related party	501	638
Other current assets	758	486
Total current assets	14,819	10,243
Property and equipment -		
Less accumulated depreciation of \$13,600 and \$15,292	12,608	13,844
Other assets	445	394
Total Assets	\$ 27,872	\$ 24,481
	=====	=====
Liabilities		
Current liabilities:		
Accounts payable	\$ 2,378	\$ 2,762
Accrued expenses	3,582	4,546
Current portion of term loan	1,576	1,576
Deferred revenue	1,057	1,057
Total current liabilities	8,593	9,941
Deferred revenue	4,228	8,863
Long-term convertible debt	16,077	16,260
Term loan	2,758	1,970
Bank promissory note	-	5,000
Commitments (see notes)		
Series D convertible redeemable preferred stock; par value \$.001; designated 20,000 shares; 0 shares issued as of June 30, 2001	-	-
Stockholders' Deficit		
Common stock, par value \$.01; authorized 80,000,000 shares:		
Issued 34,489,459 and 34,744,880 shares as of		
December 31, 2000 and June 30, 2001, respectively	346	350
Additional paid-in capital	154,646	157,354
Accumulated deficit	(157,972)	(173,085)
Treasury stock at cost, 85,000 shares at December 31, 2000 and 250,000 shares at June 30, 2001	(804)	(2,172)
Total stockholders' deficit	(3,784)	(17,553)
Total Liabilities and Stockholders' Deficit	\$ 27,872	\$ 24,481
	=====	=====

The accompanying notes are an integral part of the consolidated financial statements.

ORGANOGENESIS INC.

Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2000	2001	2000	2001
	(Restated Note 2)		(Restated Note 2)	
REVENUES:				
Research, development and milestone support from related party	\$ 5,265	\$ 265	\$ 5,529	\$ 529
Product sales to related party	685	1,730	1,331	3,565
Research and development grants	290	101	474	513
Other revenues	53	33	120	33
Total Revenues	6,293	2,129	7,454	4,640
Costs and Expenses:				
Cost of product sales to related party	1,557	2,837	3,024	5,033
Research and development	4,368	4,296	8,410	8,952
General and administrative	2,072	3,139	3,854	4,878
Total Costs and Expenses	7,997	10,272	15,288	18,863
Loss from operations	(1,704)	(8,143)	(7,834)	(14,223)
Other income (expense):				
Interest income	389	25	576	123
Interest expense	(468)	(493)	(947)	(1,013)
Net loss before cumulative effect of change in accounting principle	(1,783)	(8,611)	(8,205)	(15,113)
Cumulative effect of adopting Staff Accounting Bulletin 101 ("SAB 101")	-	-	(6,342)	-
Net loss	\$ (1,783)	\$ (8,611)	\$ (14,547)	\$ (15,113)
Net loss per common share - basic and diluted before cumulative effect of change in accounting principle	\$ (0.05)	\$ (0.25)	\$ (0.25)	\$ (0.44)
Cumulative effect of adopting SAB 101	-	-	(0.20)	-
Net loss per common share - basic and diluted	\$ (0.05)	\$ (0.25)	\$ (0.45)	\$ (0.44)
Weighted average number of common shares outstanding - basic and diluted	34,043,931	34,537,060	32,653,389	34,466,353

The accompanying notes are an integral part of the consolidated financial statements.

ORGANOGENESIS INC.

Consolidated Statements of Cash Flows
(Unaudited, in thousands)

	For the Six months Ended June 30,	
	2000 (Restated Note 2)	2001
Cash flows from operating activities:		
Net loss	\$(14,547)	\$(15,113)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	886	1,692
Issuance of stock options for services	-	74
Amortization of warrants and deferred debt issuance costs as interest expense relating to long-term convertible debt	243	234
Cumulative effect of adoption of SAB 101	6,342	-
Issuance of common stock for interest on convertible debt	696	619
Changes in assets and liabilities:		
Inventory	43	(193)
Other current assets and receivable from related party	(93)	135
Accounts payable	(682)	384
Accrued expenses and other current liabilities	(1,295)	964
Deferred revenue	(528)	4,635
Cash used in operating activities	(8,935)	(6,569)
Cash flows from investing activities:		
Capital expenditures	(1,878)	(1,308)
Capital expenditures reimbursed from related party	-	(1,620)
Sales and maturities of investments	2,697	2,644
Cash provided by (used in) investing activities	819	(284)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of term loan	-	(788)
Preferred stock redeemed in cash	(6,180)	-
Proceeds from sale of common stock - net	15,930	1,560
Proceeds from exercise of stock options	10,990	459
Purchase of treasury stock	-	(1,368)
Cash provided by (used in) financing activities	20,740	(137)
Increase (decrease) in cash and cash equivalents	12,624	(6,990)
Cash and cash equivalents, beginning of period	5,727	9,539
Cash and cash equivalents, end of period	\$ 18,351	\$ 2,549
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Interest paid in cash during the period	\$ 164	\$ 218

The accompanying notes are an integral part of the consolidated financial statements.

ORGANOGENESIS INC.

Notes to Consolidated Financial Statements
(Unaudited)1. Basis of Presentation

The accompanying unaudited consolidated financial statements of Organogenesis Inc. have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented. The results of operations for the six months ended June 30, 2001 are not necessarily indicative of the results to be expected for the year ending December 31, 2001.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Form 10-K for the year ended December 31, 2000 as filed with the Securities and Exchange Commission.

Certain reclassifications have been made to the prior period financial statements to conform to the current presentation.

2. Revenue Recognition

We previously recognized up front non-refundable research and development support payments as revenue when received. During the year ended December 31, 2000, the Company changed its method of accounting for up front non-refundable research and development support payments to recognize such amounts over the term of the related collaboration with Novartis Pharma AG ("Novartis"). This change in accounting principle is in accordance with guidance provided in SEC Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" (SAB 101), which was issued in December 1999 and summarizes certain of the Staff's views in applying generally accepted accounting principles to revenue recognition in financial statements. We adopted SAB 101 in the fourth quarter of 2000, retroactive to January 1, 2000, and recorded the cumulative effect of a change in accounting principle related to all up front non-refundable research and development support payments recognized in prior periods of \$6,342,000. Of this amount, \$1,057,000 was recognized as revenue in 2000, \$529,000 was recognized as revenue during the first half of 2001 and the remaining \$4,756,000 will be recognized ratably through December 2005, in accordance with SAB 101's guidance.

Revenues from non-refundable milestone payments are recognized when proceeds are received and the related costs and effort are considered substantive. No milestone revenues from the receipt of milestone payments were recorded during the six months ended June 30, 2001.

Revenue from product sales are recognized upon shipment after risk of ownership passes to the buyer, collection is probable and we have no performance obligations. Product revenues which are performance based are deferred until performance is achieved. Revenues from product sales for the second quarter of 2001 totaled \$1,730,000. At June 30, 2001, we had \$97,000 of deferred performance based revenue.

Revenue for funding received from Novartis for reimbursement of manufacturing facility expenditures is recognized over the period that the completed manufacturing facility is used for production of Apligraf to be sold to Novartis. No revenues have been recognized to date. The funding will be used to support facility investment needed for the approval and sale of Apligraf in the European Union. During the six months ended June 30, 2001, we received \$5,066,000 from Novartis for reimbursement of manufacturing facility costs of which \$1,620,000 was spent during the six months ended June 30, 2001 and \$448,000 was spent in prior periods.

Revenue from grants is recognized to the extent of allowable costs incurred. We have recorded revenue of \$513,000 for the six months ended June 30, 2001, of which \$410,000 relates to a grant under the Advanced Technology Program of the National Institute for Standards and Technology (refer to the "Grant Commitment" footnote) and \$103,000 relates to other research grants.

3. Net Loss Per Common Share

Net loss per common share (basic and diluted) is based on the weighted average number of common shares outstanding during each period. Potentially dilutive securities at June 30, 2001 include: stock options outstanding to purchase 3,098,397 common shares; warrants to purchase 900,000 common shares; debt convertible into 1,629,759 common shares; and the exercise of a \$10,000,000 equity security put with Novartis, which sale will close on or about September 28, 2001; however, such securities have not been included in the net loss per common share calculation because their effect would be antidilutive. Potentially dilutive securities at June 30, 2000 included: stock options outstanding to purchase 4,047,068 common shares; warrants to purchase 900,000 common shares; and debt convertible into 1,913,349 common shares; however, such securities have not been included in the net loss per common share calculation because their effect would be antidilutive.

4. Inventory

Inventory is stated at the lower of cost or market, cost being standard cost, which approximates the first-in, first-out method of accounting. Inventory, at net realizable value, consisted of the following (in thousands):

	December 31, 2000	June 30, 2001
	-----	-----
	(unaudited)	
Raw materials	\$ 488	\$ 365
Work in process	889	1,205
	-----	-----
	\$1,377	\$1,570
	=====	=====

5. Related Party Transactions

In January 1996, we entered into a collaborative agreement with Novartis granting Novartis exclusive global marketing rights to Apligraf. Under the agreement, we have received equity investments, non-refundable research, development and milestone support payments, product payments and funding for publication study programs. Product and funding for publication study programs are included under the captions "Product sales to related party" and "Other revenues" in our financial statements.

In February 2001, we amended our collaborative agreement with Novartis, effective January 2, 2001. The amended agreement:

- o Grants Novartis the right to purchase an exclusive option to negotiate terms to license Organogenesis's product Vitrix(TM) and also for a second living dermal replacement product currently in Organogenesis research;

- o Provides Organogenesis with significantly higher payments for units of Apligraf;
- o Grants Organogenesis the right for three years to sell, at its discretion, to Novartis up to \$20 million in equity;
- o Includes funding support from Novartis to upgrade Organogenesis's manufacturing facility and for the facility investment needed for approval and sale of Apligraf in the European Union;
- o Includes funding support for Apligraf clinical development activities (e.g., to further broaden its approved uses); and
- o Includes development funding support for each living dermal replacement product for which Novartis purchases an option to commence licensing negotiations.

We supply Novartis's global requirements for Apligraf and receive a product payment based on net product sales. Receivable from related party consists of amounts due on product sales to Novartis, funding of certain programs by Novartis and reimbursement of certain test costs related to the manufacturing of the product. Novartis is billed weekly for payments due on product sales and on an as incurred basis for other billings.

On June 29, 2001, we exercised a \$10,000,000 equity security put with Novartis, which sale will close on or about September 28, 2001. We anticipate that the securities sold will be 10,000 shares of Series D convertible redeemable preferred stock. Series D preferred stock may be converted at any time into common stock at 90% of the volume-weighted average closing price for the 20 consecutive trading days prior to the close on or about September 28, 2001 ("conversion price") at the option of the holder, but prior to the date that we may give notice to redeem all outstanding Series D preferred stock for cash. We may redeem at any time Series D preferred stock into common stock at the conversion price, into cash at \$1,000 per share or any combination thereof. The Series D preferred stock pays no dividends and has no voting rights. In the event of any liquidation, dissolution, merger, sale of the Company, or winding up of the affairs of the Company, the holder of the shares of Series D stock shall be entitled, before any distribution is made upon the common stock, to be paid an amount equal to \$1,000 per share or if such distribution is insufficient, than all assets of the Company shall ratably be distributed based on the number of shares of Series D preferred stock held. We are required to file a registration statement for the common stock redeemable under the Series D preferred stock by the tenth business day following the close. We may notify Novartis of our intention to rescind this exercise prior to September 12, 2001.

As a result of previous equity investments made in prior years, Novartis holds approximately 1.9% of outstanding shares as of June 30, 2001.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2000	June 30, 2001
	-----	-----
	(unaudited)	
Compensation and employee benefits	\$1,869	\$1,714
Accrued Severance	-	1,075
Professional services	734	810
Accrued interest	368	312
Other	611	635
	-----	-----
	\$3,582	\$4,546
	=====	=====

7. Term Loan Agreement

In November of 1999, we entered into a \$5,000,000 term loan agreement with a commercial bank to finance the purchase of certain equipment, leasehold improvements and other items. Borrowings under the term loan are collateralized by a security interest in the items financed. The agreement provides for repayment of the principal amount of the loan in 12 equal quarterly installments commencing December 29, 2000, with final payment due on September 30, 2003. The loan bears interest at a fluctuating rate per annum that is equal to the prime rate in effect from time to time, or we may elect that all or any portion of any term loan be made as a LIBOR loan with an interest period of one month, two months, three months or six months with the interest rate being equal to LIBOR plus an applicable margin (175 to 225 basis points). We are required to comply with certain covenants relating to our outstanding term loans, involving limitations on future indebtedness, dividends and investments, and to maintain certain financial covenants pertaining to liquidity, capital base, and debt

service coverage (or, alternatively, maintaining a minimum unencumbered cash balance). We borrowed approximately \$4,728,000 against this term loan to finance certain research, manufacturing and office equipment and leasehold improvements. We had \$3,546,000 outstanding at June 30, 2001. The weighted average interest rate paid during this period was 7.82%. This borrowing was collateralized by a security interest in the fixed assets financed. On July 6, 2001, we paid \$3,562,000 which represented all outstanding principal and accrued interest under this term loan.

On June 29, 2001, we entered into a \$5,000,000 revolving credit agreement with a commercial bank and borrowed the full \$5,000,000 which was held in a cash collateral account pending payment in full of all obligations and release of all liens under the term loan. The cash collateral account was classified as restricted cash at June 30, 2001. The revolving credit agreement provides for loans to be used for general business purposes with the interest rate being equal to the bank's prime rate plus two percent. Loans made under the revolving credit agreement are collateralized by a security interest in all of our assets. Subsequent to June 30, 2001, the full \$5,000,000 was released from the cash collateral account and \$3,562,000 was used to repay the term loan and the balance will be used for general corporate purposes. The revolving credit agreement will become payable in a single installment on June 29, 2003. Additional terms under this agreement require us to keep \$5,000,000 in a cash collateral account at all times after we receive the proceeds from the equity security put with Novartis, which sale will close on or about September 28, 2001, until we pay all outstanding principal and accrued interest under this revolving credit agreement.

8. Grant Commitment

In November 1999, we received notice of a \$2,000,000 grant under the Advanced Technology Program of the National Institute for Standards and Technology ("NIST") to help support development of an effective liver assist device prototype, of which we have received \$1,300,000 and expect to receive the remaining amount over the period through December 2001. This grant requires that the United States federal government can access for its own purpose technology developed using the funding. A product developed based on the funding from the NIST grant must be manufactured substantially in the United States. In addition, we are subject to regular audit and reporting requirements. We have recorded revenue of \$101,000 and \$410,000 for the three and six months ended June 30, 2001, respectively, relating to this research grant.

9. Stockholders' Equity:

Preferred Stock

On June 29, 2001, we exercised a \$10,000,000 equity security put with Novartis, which sale will close on or about September 28, 2001. We anticipate that the securities sold will be 10,000 shares of Series D convertible redeemable preferred stock. Series D preferred stock may be converted at any time into common stock at 90% of the volume-weighted average closing price for the 20 consecutive trading days prior to the close on or about September 28, 2001 ("conversion price") at the option of the holder, but prior to the date that we may give notice to redeem all outstanding Series D preferred stock for cash. We may redeem at any time Series D preferred stock into common stock at the conversion price, into cash at \$1,000 per share or any combination thereof. The Series D preferred stock pays no dividends and has no voting rights. In the event of any liquidation, dissolution, merger sale of the Company, or winding up of the affairs of the Company, the holder of the shares of Series D preferred stock shall be entitled, before any distribution is made upon the common stock, to be paid an amount equal to \$1,000 per share or if such distribution is insufficient, then all assets of the Company shall ratably be distributed based on the number of shares of Series D preferred stock held. We are required to file a registration statement for the common stock redeemable under the Series D preferred stock by the tenth business day following the close. We may notify Novartis of our intention to rescind this exercise prior to September 12, 2001.

Common Stock

In April 2001, we issued 65,209 shares of common stock for payment of interest on our long-term convertible debt.

On May 4, 2001, the Securities and Exchange Commission declared effective an amendment to our shelf registration statement to sell to an underwriter up to a total of 1,900,000 shares of common stock from time to time during the two-year period ending April 2003. The number of shares sold may not be less than 5% and not more than 25% of the average trading volume of common stock on the American Stock Exchange for the previous five days. The purchase price of the shares we sell to the underwriter is the volume weighted average price for that trading day less an underwriting discount of 6% or 4.5%. In May and June 2001, we sold 237,200 shares of common stock to the underwriter yielding net proceeds of \$1,560,000 (net of an underwriters discount and offering expenses).

During the six months ended June 30, 2001, we issued 118,012 shares of common stock for the exercise of employee stock options, yielding proceeds of approximately \$459,000.

OPTIONS ISSUED TO A CONSULTANT

In May 2001, we executed an agreement granting options to purchase 35,000 shares of common stock at an exercise price of \$8.10 per share to a consultant. These options were issued fully vested and exercisable, with an expiration of five years. We recorded an expense of \$74,000 relating to the fair value of these options (using an option-pricing model).

10. Treasury Stock:

In December 2000, the Board of Directors authorized a common stock repurchase program for up to 500,000 shares. Repurchases are allowed through open-market transactions that will provide us with shares for general corporate purposes. During the first half of 2001, we repurchased 165,000 shares of common stock for an aggregate purchase price of approximately \$1,367,000. The stock repurchase program may be discontinued at any time.

We had in treasury 85,000 shares of common stock at a cost of \$804,000 and 250,000 shares of common stock at a cost of \$2,172,000, at December 31, 2000 and June 30, 2001, respectively.

11. Severance Agreement:

In May 2001, we entered into a separation of employment agreement with a former executive officer, which resulted in the recording of a one-time severance expense of \$1,233,000 during the quarter ended June 30, 2001. The separation of employment agreement provides for amounts to be paid over two years and supercedes the previous employment agreement. It has been filed as exhibit 10(ff) to this Form 10Q.

12. New Accounting Pronouncements:

In July 2001, the Financial Accounting Standards Board issued SFAS No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 requires that ratable amortization of goodwill be replaced with periodic tests of the goodwill's impairment and that intangible assets other than goodwill be amortized over their useful lives. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001 and for all business combinations accounted for by the purchase method for which the date of acquisition is after June 30, 2001. The provisions of SFAS No. 142 will be effective for fiscal years beginning after December 15, 2001, and will thus be adopted by us, as required, in fiscal year 2002. We do not expect that the application of SFAS No. 141 and SFAS No. 142 will have a material impact on our financial position or results of operations.

ORGANOGENESIS INC.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Form 10-Q contains forward-looking statements that involve risks and uncertainties. Forward-looking statements include information on:

- o Our business outlook and future financial performance;
- o Anticipated profitability, revenues, expenses and capital expenditures;
- o Anticipated research, development, clinical, regulatory and reimbursement progress;
- o Future funding and expectations as to any future events; and
- o Other statements that are not historical fact and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties.

Although we believe that our plans, intentions and expectations reflected in or suggested by such forward-looking statements are reasonable, we can give no assurance that such plans, intentions or expectations will be achieved. When considering such forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this Form 10-Q and in other publicly available filings with the US Securities and Exchange Commission ("SEC"), such as our Annual Report on Form 10-K for the year ended December 31, 2000. The risk and other factors noted throughout this Form 10-Q could cause our actual results to differ materially from the results contained in any forward-looking statements.

In Management's Discussion and Analysis ("MD&A"), we explain the general financial condition and results of operations for Organogenesis Inc. As you read this MD&A, referring to our consolidated financial statements contained in Item 1 of this Form 10-Q may be helpful. Results of operations may vary significantly from quarter to quarter depending on, among other factors, the progress of our research and development efforts, the receipt of research, development and milestone support payments, if any, from Novartis, product revenues, manufacturing costs, the timing of certain expenses and the establishment of additional collaborative agreements, if any.

Overview of Organogenesis Inc.

Organogenesis Inc. - a tissue engineering company - designs, develops and manufactures medical products containing living cells and/or natural connective tissue. We are the developer and manufacturer of the only US Food and Drug Administration ("FDA") approved mass-produced living product targeting large markets. Our product and research portfolio features living tissue replacements, bio-engineered collagen matrix products and other tissue-engineering programs leveraging our expertise with living cells.

PRODUCTS WITH MARKETING AUTHORIZATION

Our lead product, Apligraf living skin substitute, is FDA approved and marketed in the US for two uses: treatment of healing resistant venous leg ulcers, approved May 1998, and treatment of healing resistant diabetic foot ulcers, approved June 2000. Novartis Pharma AG ("Novartis") has exclusive global Apligraf marketing rights. In recent months, decisions made at the national and regional level have expanded access to Apligraf by Medicare-insured patients. Apligraf is also available in select international markets. In April 2001, Novartis submitted the regulatory filing for marketing approval across the European Union.

A pivotal trial is underway to assess the ability of Apligraf to reduce scarring after skin cancer surgery. We expect to complete this trial and submit to the FDA for marketing approval in 2002. As a living skin substitute, we believe Apligraf has a number of additional potential uses.

Apligraf(R) is a registered trademark of Novartis.

We are leveraging our FortaFlex(TM) bioengineered collagen matrix technology into a family of products. We recently achieved FDA marketing clearance for our FortaPerm(TM) surgical sling and our PuraPly(TM) wound dressing. A third product, FortaGen(TM) is under review at the FDA. Initial product commercialization is expected to begin this fall. Royce Medical Company has marketing rights for the US non-hospital market for PuraPly.

OUR PIPELINE

Our research and development pipeline includes a living dermal replacement product candidate, Vitrix(TM), anticipated to have multiple potential uses. We have initiated a clinical study for Vitrix in the treatment of deep diabetic foot ulcers. Our pipeline also includes a coronary vascular graft and a liver assist device, both currently in animal studies, as well as, nearer term, other potential applications of our FortaFlex technology.

RESULTS OF OPERATIONS

We are currently at a low volume production for Apligraf. Although revenues are ramping-up as evidenced by the unit growth in each quarter, we expect production costs to exceed product sales for at least the next nine months due to the high costs associated with low unit volume production. We expect production volume to increase due to recent Medicare progress with coverage for Apligraf, FDA approval of Apligraf for use in diabetic foot ulcers and expanded Novartis sales and marketing support.

REVENUES

Product revenues for the quarter ended June 30, 2001 increased 153% to 1,730,000, from \$685,000 for the comparable quarter last year. Product revenues for the six-month period ended June 30, 2001 increased 168% to 3,565,000, from 1,331,000 for the comparable period last year. These increases were due to significantly higher payments received for units of Apligraf sold to Novartis under the amended collaborative agreement that became effective January 2, 2001 and to increased unit sales of Apligraf to Novartis. We expect Apligraf commercial sales to continue to increase. Research, development and milestone support from related party for the three and six months ended June 30, 2000 includes a \$5,000,000 payment from Novartis for achievement of a milestone related to the diabetic foot ulcer indication. No such payments have been received in 2001.

COSTS AND EXPENSES

Cost of product sales: Cost of product sales for the quarter ended June 30, 2001 increased 82% to \$2,837,000, from \$1,557,000 for the comparable quarter last year. Cost of product sales for the six-month period ended June 30, 2001 increased 66% to 5,033,000, from \$3,024,000 for the comparable period last year. These increases were due to increased unit sales of Apligraf to Novartis, additional scrap costs and higher allocations of depreciation and occupancy costs. Cost of product sales includes the direct costs to manufacture, quality inspect and package Apligraf and an allocation of our production-related indirect costs. Cost of product sales continues to exceed product sales due to the high costs associated with low volume production. We expect production volume to increase and our margins to continue to improve during 2001. We expect that we will have to revise standard costs and the allocation of costs to product sales in the future as we continue to modify our manufacturing processes.

Royce is a registered trademark of Royce Medical Company

Research and development: Research and development expenses ("R&D") consist of costs associated with research, development, clinical, process development, facilities and engineering support excluding the allocation of our production related indirect costs. R&D expenses for the quarter ended June 30, 2001 decreased 2% to \$4,296,000, from \$4,368,000 for the comparable quarter last year. R&D expenses for the six-month period ended June 30, 2001 increased 6% to \$8,952,000, from \$8,410,000 for the comparable period last year, due to: increased clinical outside service and consulting costs related to further broadening Apligraf uses; increased process development costs related to manufacturing improvement programs and increased product development costs related to our Technology Ventures business unit. We expect that R&D expenses will continue to increase moderately during 2001.

General and administrative expenses: General and administrative expenses ("G&A") include the costs of our corporate, finance, information technology and human resource functions. G&A expenses for the quarter ended June 30, 2001, excluding a one-time severance expense of 1,233,000, decreased 1% to \$1,906,000, from \$2,072,000 for the comparable quarter last year. G&A expenses for the six-month period ended June 30, 2001, excluding a one-time severance expense, decreased 5% to \$3,645,000 from \$3,854,000 for the comparable period last year. These decreases were due to lower occupancy and consulting costs. We expect that G&A expenses will decrease during 2001 as we expect to use less outside services. Severance expense for the quarter and six month period ended June 30, 2001 represents a one-time expense of \$1,233,000 related to the separation of employment of a former executive officer. No severance expense was recorded for the comparable periods last year.

Other income and expense: Interest income for the quarter ended June 30, 2001 decreased 94% to \$25,000, from \$389,000 for the comparable quarter last year. Interest income for the six-month period ended June 30, 2001 decreased 79% to \$123,000 from \$576,000 for the comparable period last year. These decreases were primarily due to the decrease in funds available for investment. Interest expense for the quarter ended June 30, 2001 increased 5% to \$493,000, from \$468,000 for the comparable quarter last year. Interest expense for the six-month period ended June 30, 2001 increased 7% to \$1,013,000 from \$947,000 for the comparable period last year. These increases were due to no interest expense capitalization during the six-month period ended June 30, 2001, compared to \$192,000 capitalized for the comparable period last year.

NET LOSS

As a result of the net effects described above, our net loss for the quarter ended June 30, 2001 was \$8,611,000 or \$0.25 per share (basic and diluted), compared to \$1,783,000, or \$0.05 per share (basic and diluted), for the comparable quarter last year. Our net loss for the six-month period ended June 30, 2001 was \$15,113,000 or \$0.44 per share (basic and diluted), compared to \$8,205,000, or \$0.25 per share (basic and diluted), before the cumulative effect of change in accounting principle, for the comparable period last year, and a net loss effected for the change in accounting principle of \$14,547,000, or \$0.45 per share (basic and diluted), for the comparable period last year.

Capital Resources and Liquidity

FUNDS USED IN OPERATIONS

At June 30, 2001, we had unrestricted cash, cash equivalents and investments in the aggregate amount of \$2,549,000, compared to \$12,183,000 at December 31, 2000. Cash equivalents consist of money market funds, which are highly liquid and have original maturities of less than three months. Investments consist of securities that have an A or A1 rating or better with a maximum maturity of two years. Cash used in operating activities for the six months ended June 30, 2001 was \$6,569,000, primarily for funding our net loss. Cash used in operating activities for the six months ended June 30, 2000 was \$8,935,000,

primarily for funding our net loss, offset by \$5,000,000 cash received from Novartis in advance of achievement of a milestone related to the diabetic foot ulcer indication.

CAPITAL SPENDING

Capital expenditures were \$2,928,000 (of which \$1,620,000 was reimbursed by Novartis) and \$1,878,000 during the six months ended June 30, 2001 and 2000, respectively, primarily related to the further build-out of existing facilities to support Apligraf manufacturing. We will continue to utilize funds during 2001 to expand our existing facility in the areas of Apligraf manufacturing, packaging and other process development improvement programs, including funds which we will receive from Novartis to upgrade our manufacturing facility and for the facility investment needed for approval and sale of Apligraf in the European Union.

NOVARTIS SUPPORT

During the first quarter of 2001, Novartis provided funding support of \$5,066,000 for upgrades to our manufacturing facility and for the facility investment needed for approval and sale of Apligraf in the European Union. We have recorded the full amount of this funding as deferred revenue for the period ended June 30, 2001. Revenue will be recognized over the period that the completed manufacturing facility is used for production of Apligraf to be sold to Novartis. We have spent \$1,620,000 during the six months ended June 30, 2001 and \$448,000 was spent in prior periods.

FINANCING

From inception, we have financed our operations substantially through private and public placements of equity securities, as well as receipt of research support and contract revenues, interest income from investments, sale of products and receipt of royalties. During the six months ended June 30, 2001, financing activities used cash of \$137,000 primarily due to the purchase of treasury stock totaling \$1,368,000 and payment of a term loan for \$788,000, partially offset by cash received from the exercise of stock options for \$459,000 and the sale of common stock that generated net proceeds of \$1,560,000. Financing activities provided cash of \$20,740,000 for the six months ended June 30, 2000 primarily from the sale of common stock that generated net proceeds of \$15,930,000 and the exercise of stock options that generated \$10,990,000, partially offset by the redemption of Series C redeemable convertible preferred stock in cash for \$6,180,000.

LIQUIDITY

Based upon our current plans, we believe existing working capital at June 30, 2001, together with the proceeds of product and other revenues in 2001 and proceeds available from sales of shares to the underwriter under the shelf registration, our exercise of a \$10,000,000 equity security put with Novartis on June 29, 2001, which sale will close on or about September 28, 2001 and exercising the remaining \$10,000,000 equity security put with Novartis, which is at our discretion, will be sufficient to finance operations through at least the first quarter of 2002. We expect to raise additional funds in 2001 through equity financing. However, this statement is forward-looking and changes may occur that would significantly decrease available cash before such time. Factors that may change our cash requirements include:

- o Sales volume forecasts not achieved;
- o Delays in obtaining regulatory approvals of products in different countries, if needed, and subsequent timing of product launches;
- o Delays in commercial acceptance and reimbursement when product launches occur;
- o Changes in the progress of research and development programs; and

- o Changes in the resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies.

Any of these events could adversely impact our capital resources, requiring us to raise additional funds. Management believes that additional funds may be available through equity or debt financing, strategic alliances with corporate partners, capital lease arrangements, or other sources of financing in the future. There can be no assurances that these funds will be available when required on terms acceptable to us, if at all. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs or license to third parties certain products or technologies that we would otherwise undertake ourselves, resulting in a potential adverse effect on our financial condition and results of operations.

ADDITIONAL CAUTIONARY CONSIDERATIONS

We are subject to risks common to entities in the biotechnology industry, including, but not limited to, the following uncertainties:

- o Continued operating losses and the time required to achieve profitability;
- o Market acceptance of our products and successful marketing and selling of Apligraf by Novartis;
- o Development by competitors of new technologies or products that are more effective than ours;
- o Dependence on our strategic relationships to market our products;
- o Compliance with FDA regulations and similar foreign regulatory bodies;
- o Protection of proprietary technology through patents and risks of infringement claims by third parties;
- o Manufacture and sale of products in sufficient volume to realize a satisfactory margin;
- o Continued availability of raw material for products;
- o Product quality issues which could lead to product recalls;
- o Dependence on and retention of key personnel;
- o Availability of sufficient product liability insurance;
- o Adequate third-party reimbursement for products;
- o Stock price volatility and fluctuation;
- o Availability of additional capital on acceptable terms, if at all;
- o Affect of anti-takeover measures on the value of our stock;
- o Affect of outstanding options, warrants and convertible debt on the value of our stock; and
- o Risk of failure of clinical trials for future indications of Apligraf and for Vitrix and other products.

ITEM 3 QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The exposure of market risk associated with risk-sensitive instruments is not material, as our sales are transacted primarily in United States dollars, we invest primarily in money market funds and we have not entered into hedging transactions.

ORGANOGENESIS INC.

PART II - OTHER INFORMATION

Item 4. Submission of Matters to a Vote of Security Holders

We held our Annual Meeting for Stockholders on June 21, 2001. At the meeting, Messrs. James J. Apostolakis, Albert Erani, David A. Gardner, Bernard A. Marden, Glenn Nussdorf, Bjorn R. Olsen, Ms. Marguerite A. Piret, Michael L. Sabolinski and Anton E. Schrafl, were re-elected as Directors and Messr. Richard J. Ulevitch was newly elected as Director. The vote with respect to each nominee is set forth below:

	Votes For	Votes Against
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Mr. Apostolakis	29,820,664	240,356
Mr. Erani	25,543,392	4,517,628
Mr. Gardner	27,728,385	2,332,635
Mr. Marden	27,659,900	2,401,120
Mr. Nussdorf	27,727,773	2,333,247
Dr. Olsen, M.D.	29,019,022	1,041,998
Ms. Piret	29,788,596	272,424
Mr. Sabolinski, M.D.	29,821,287	239,733
Dr. Schrafl	29,819,240	241,780
Dr. Ulevitch	29,846,247	214,773

In addition, the stockholders authorized the ratification of the selection by the Board of Directors of PricewaterhouseCoopers LLP as our independent accountants for the 2001 fiscal year; by a vote of 27,600,103 shares for, 2,392,148 shares against and 68,769 shares abstaining.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

10(ff) Severance Agreement between the Company and Mr. Philip M. Laughlin dated May 15, 2001.

10(gg) Revolving Credit Agreement and Secured Revolving Promissory Note between the Company and Berkshire Bank dated June 29, 2001.

(b) Reports on Form 8-K filed during the quarter ended June 30, 2001.

A current report on Form 8-K dated May 16, 2001 was filed by the Registrant announcing the appointment of Dr. Michael L. Sabolinski, M.D., to the positions of President and Chief Executive Officer and to the Board of Directors, replacing Philip M. Laughlin who resigned from these positions.

A current report on Form 8-K dated May 8, 2001 was filed by the Registrant announcing that it has entered into an underwriting agreement with UBS Warburg LLC

A current report on Form 8-K dated March 8, 2001, as amended April 24, 2001, was filed by the Registrant reporting the following:

- o An announcement that the federal Health Care Financing Administration, which administers Medicare, has classified Apligraf as a biologic for reimbursement purposes when applied in a doctor's office.
- o An announcement of the signing of an amendment, effective January 2, 2001, to the Registrant's 1996 agreement with Novartis AG.
- o Other matters discussed on a conference call dated February 27, 2001.

ORGANOGENESIS INC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Organogenesis Inc.
(Registrant)

Date: August 14, 2001

/S/ Michael L. Sabolinski

Michael L. Sabolinski, M.D., President
and Chief Executive Officer
(Principal Executive Officer)

Date: August 14, 2001

/S/ John J. Arcari

John J. Arcari, Vice President, Finance and
Administration, Chief Financial Officer
(Principal Financial and Accounting Officer)